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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,379	02/19/2004	William S. Hurst	TR-6009	6415

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EXAMINER	
CHIMIAK, EMILY ANN	
ART UNIT	**PAPER NUMBER**
1791	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,379	HURST ET AL.	
	Examiner	Art Unit	
	Emily Chimiak	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,21-23,25-28,30,37-39,41,42,44-47,49-51,57,58 and 77-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 5 and 77-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. '522 in view of Savitski et al. and Abrams (US 6331184).

As to claim 1, Peters et al. discloses a method for assembling a medical device comprising:

- providing a first article of a polymeric material; providing a second article of a polymeric material;
- contacting and attaching the first article with the second article along an interface area; and exposing the first article and the second article to a specific portion of the infrared spectrum where the polymeric material of the first article and the polymeric material of the second article absorb infrared energy in order to generate sufficient heat to create a bond between the first article and the second article

(See figure 5a-5f, column 8, lines 6-56).

Peters et al. discloses fitting a heat shrinkable tube over the balloon but does not disclose that the heat shrinkable tube functions as a heat shield over the bond area.

However, Savitski et al. discloses applying performing coupling 40 (equated to the heat shrinkable tube disclosed by Peters et al. and the heat shield disclosed by applicant) with a predetermined distribution of absorbing material in order to form uniform welds with sufficient molten plastic materials wherein the distribution of radiation absorbing material depending on the joint configuration and particular materials to be joined (figure 3 and [0078]).

It would have been obvious to one of ordinary skill in the art at the time of invention to use the heat shield configuration of Savitski et al. in the assembling method disclosed by Peters et al. in order to afford heating of certain parts of the weld to provide sufficient molten plastic material.

Peter et al. discloses that the outer tube (35) can be made of a flexible polymer and that balloon (37) may be made of conventional materials such as PEBAX, but it is unclear if (35) and (37) consist of styrene-ethylene-butene-styrene block co-polymer (SEBS).

However, Abrams discloses that a highly flexible polymer that is functionally equivalent to Pebax in the catheter art is SEBS (48-64).

It would have been obvious to one of ordinary skill in the art at the time of invention to use SEBS for the outer tube and balloon disclosed by Peters as modified by Savitski et al. because Abrams teaches that SEBS is known in the art as flexible and a functional equivalent of Pebax.

As to claim 5, Peters et al. discloses a method wherein the first article is a medical tubing and the second article is a medical tubing (column 8, lines 9-11).

As to claims 77-80, the rejection of claim 1 is relied on. It is noted that a selectively tinted heat shrink tube will maintain a desired functional geometry of the first and second articles (claim 77), prevent exposure of the non-bond area to infrared energy (claim 78), prevent distortion of the first and second articles at the interface area (claim 79) and surround the interface area (claim 80).

5. Claims 1, 5, 21, 26-28, 30, 41, 42, 45-47 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman et al. (2003/0201059) in view of Savitski et al. and Abrams.

As to claim 1, Holman et al. discloses a method for assembling a medical device comprising:

- providing a first article of a polymeric material; providing a second article of a polymeric material
- contacting and attaching the first article 12 with the second article 16 along a n interface area; and
- exposing the first article and the second article to a specific portion of the infrared spectrum where the polymeric material of the first article and the polymeric material of the second article absorb infrared energy in order to generate sufficient heat to create a bond between the first article and the second article

(See paragraph 0034-0039).

Holman et al. discloses that a material can be added to the catheter to absorb a predetermined wavelength of energy in a variety of ways, but does not disclose fitting a heat shield over the bond area.

However, Savitski et al. discloses applying performing coupling 40 (heat shield) with a predetermined distribution of absorbing material in order to form uniform welds with sufficient molten plastic materials (figure 3 and [0078]).

It would have been obvious to one of ordinary skill in the art at the time of invention to use the heat shield configuration of Savitski et al. in the assembling method disclosed by Holman in order to afford heating of certain parts of the weld to provide sufficient molten plastic material.

Holman et al. discloses that the various components of catheter 10 is preferably constructed from thermoplastic materials such as PEBAX ([0036]), but it is unclear whether Holman teaches using SEBS. One of ordinary skill in the art reading Holman et al. as a whole would readily appreciate that the reference is not concerned with the particular plastic used for the various components because it is not even limited to thermoplastic materials, which in itself covers a broad range of plastics.

Abrams teaches that a functional equivalent of Pebax is SEBS. it would have been obvious to one of ordinary skill in the art at the time of invention to use SEBS for the various components of Holman et al. as modified by Savitski because Abrams teaches that they are functional equivalents.

As to claim 21, the rejection of claim 1 above is relied on.

As to claims 5, 30 and 42 Holman et al. discloses a method wherein the first article is a medical tubing and the second article is a medical tubing (paragraph 0034, 0068). As to claims 21 and 41, Holman et al. discloses a method for assembling a medical device comprising the steps of: providing a first article 12 of a polymeric material; providing a second article 16 of a polymeric material; applying an infrared absorbing pigment to the first article and the second article to define an interface area (paragraph 0039); contacting the first article with the second article along the interface area; and bonding the first article to the second article along the interface area using infrared exposure (paragraph 0034-0039). As to claims 26-28 and 45-47, Holman et al. discloses a method wherein the infrared absorbing pigment is placed on a first portion of the first or second article in a first concentration and in a second portion of the surface

in a second concentration lower than the first concentration; applying a first infrared exposure to the first portion of the surface to create a seal, and applying a second infrared exposure higher than the first infrared exposure to the second portion of the surface to create a second seal (paragraphs 0058-0067, 0034-0045, 0013-0018, figure 14). As to claim 51, Holman et al. discloses a method for assembling a medical device, said method comprising: providing a first article 12 of a polymeric material; providing a second article 16 of a polymeric material; providing an infrared responsive pigmented film 18; placing the infrared responsive pigmented film between the first article and the second article to define an interface area and contacting the first article with the second article; and applying infrared exposure to bond the first article and the second article (figures paragraph 0034-0039).

6. Claims 1, 3, 5, 21, 26-28, 30, 37, 38, 41, 42, 45-47, 49-51, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. '552 in view of Savatski et al., Abrams, Holman et al. (2003/0201059) and ANTEC 2000 Plastics: The Magical Solution, Volume 1: Processing, hereafter referred to as ANTEC 2000 Plastics.

As to claim 1, Peters et al. discloses a method for assembling a medical device comprising the steps of:

- providing a first article of a polymeric material; providing a second article of a polymeric material;
- contacting the first article with the second article along the interface area;
- and bonding the first article to the second article along the interface area using infrared exposure

(See figure 5a-5f, column 8, lines 6-56).

Peters et al. is silent as to applying a heat shield over the bond area and as to a method of applying an infrared absorbing pigment to the first and second articles. However, Savitski et al. discloses applying performing coupling 40 (heat shield) with a predetermined distribution of absorbing material in order to form uniform welds with sufficient molten plastic materials (figure 3 and [0078]).

It would have been obvious to one of ordinary skill in the art at the time of invention to use the heat shield configuration of Savitski et al. in the assembling method disclosed by Holman in order to afford heating of certain parts of the weld to provide sufficient molten plastic material.

Peter et al. discloses that the outer tube (35) can be made of a flexible polymer and that balloon (37) may be made of conventional materials such as PEBAX, but it is unclear if (35) and (37) consist of styrene-ethylene-butene-styrene block co-polymer (SEBS).

However, Abrams discloses that a highly flexible polymer that is functionally equivalent to Pebax in the catheter art is SEBS (48-64).

It would have been obvious to one of ordinary skill in the art at the time of invention to use SEBS for the outer tube and balloon disclosed by Peters as modified by Savitski et al. because Abrams teaches that SEBS is known in the art as flexible and a functional equivalent of Pebax.

Holman et al. discloses a method of assembling two medical tubular articles together as discussed above, and further discloses a step of applying an infrared absorbing pigment to the first article and the second article to define an interface area (paragraph 0037-0039). Holman et al. also discloses that an infrared responsive pigmented film 18 can be placed between the first article and second article to define an interface area (paragraph 0039). Application of said pigment coating or film provides each article with a desired absorption characteristic (paragraph 0035-0037). At the time of the invention it would have been obvious to a person of ordinary skill in the art to modify the method of Peters et al. by applying an infrared absorbing pigment (as a coating or film) to the first article and the second article to define an interface area as taught by Holman et al. above. Such a modification would enable the absorption characteristics of the articles of Peters et al. to be varied to a desired characteristic.

As to claim 5, the rejection above over Peter for claim 5 is relied on.

As to claim 21, the rejection of claim 1 immediately above is relied on.

As to claim 41, the rejection of claim 1 above is relied on.

As to claims 26-28, 30, 42 and 45-47, Holman et al. meets the limitations of said claims as discussed above. As to claims 3, 37, 49 and 57 examiner asserts that PTFE is a well-known material in the art, and one of ordinary skill in the art would have readily recognized its use as an infrared blocker. As to claims 38, 50, 51 and 58 Peters et al. discloses that bonding takes place as a result of infrared absorption at multiple locations along an axis (locations 40, 41, 38, 39). Since the reference discloses that the heat shield blocks non-bonding regions from infrared

exposure, the presence of "slots" at locations 40, 41, 38, 39, is inherent to the heat shield of Peters et al. because said locations are exposed to infrared light.

7. Claims 25 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. '552 in view of Savatski et al., Holman et al. and Abrams as applied to claim 21 and 41 above, and further in view of ANTEC 2000 Plastics: The Magical Solution, Volume 1: Processing, hereafter referred to as ANTEC 2000 Plastics.

As to claims 25 and 44, examiner asserts that printing is a well-known method of coating an article, including in the art of coating an infrared absorbing pigment on a polymeric article as shown by ANTEC 2000 Plastics, which discloses that printing is one of the methods of applying NIR absorber dye onto a polymer piece (col. 1 paragraphs 2 and 4). It would have been obvious at the time of invention to one of ordinary skill in the art to print infrared responsive dye as a low cost way of imparting absorptive properties to selected areas.

8. Claims 21-23 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman et al., Savatski et al. and Abrams. as applied above, and in further view of Ammann et al. '097.

Holman et al. discloses a method as discussed above, and further discloses that any known infrared absorbing pigment can be used. The reference is silent however, as to specifically using carbon black or activated charcoal. Ammann et al. discloses a method for assembling a medical device comprising: providing first and second articles of polymeric material, contacting the first article with the second article along the interface area and bonding

the two articles together using infrared radiation (figure 2, column 2, line 40 – column 4, line 8). Ammann further discloses that it is well known and preferable to use carbon black or activated charcoal as the infrared absorbing pigments at the bonding interface (column 3, lines 5-10). At the time of the invention it would have been obvious to a person of ordinary skill in the art to use either carbon black or activated charcoal as the applied infrared absorbing pigment as is well known in the art and taught by Ammann et al.

As to claim 39, Ammann et al. discloses a method wherein bonding is performed using an infrared lamp (column 3, line 63-column 4, line 7).

Response to Arguments

Applicant's arguments with respect to claims 1,3,5,21,22,23,25-28,30,37-39,41,42,44-47,49,50,51,57,58 and 77-80 have been considered but are moot in view of the new ground(s) of rejection.

As to the argument regarding exposing the first article and second article to infrared to bond them, the primary references teach such (see Peters col. 8 lines 40-45 and Holman et al. [0034]). It is noted that the Holman reference discloses bonding with a laser that transmits 1054 nm in one embodiment, and the infrared range extends from 1000 nm to 1 cm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Chimiak whose telephone number is (571)272-6486. The examiner can normally be reached on Monday-Friday 8:30-5:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571)272-6486. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EAC

Justin Fischer
/Justin Fischer/
Primary Examiner 1791